

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION**

**INSTITUTE FOR ENVIRONMENTAL
HEALTH, INC.**

Plaintiff

v.

FOOD SAFETY NET SERVICES, LTD.

Defendant.

Civil Case No. 6:21-cv-176

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Institute for Environmental Health, Inc. (“Plaintiff” or “IEH”) hereby asserts the following claims for patent infringement against Food Safety Net Services, Ltd. (“Defendant” or “FSNS”) and alleges, upon information and belief, as follows:

PARTIES

1. Plaintiff IEH is a Washington corporation with its principal place of business located in Lake Forest Park, Washington.
2. On information and belief, Defendant FSNS is a Texas corporation with its principal place of business located in San Antonio, Texas.

JURISDICTION AND VENUE

3. This claim is for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*
4. This Court has original jurisdiction over IEH’s claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).
5. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ASSERTED PATENTS

6. IEH is the owner by assignment of all right, title, and interest in U.S. Patent No. 7,534,584 (the “’584 patent”) entitled “Modular Compositing—Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents.” The U.S. Patent and Trademark Office (“USPTO”) duly and legally issued the ’584 patent on May 19, 2009. The USPTO issued a reexamination certificate for the ’584 patent on March 6, 2019. A copy of the ’584 patent is attached as Exhibit A to the Complaint. A copy of an inter partes reexamination certificate for the ’584 patent, issued March 6, 2019, is attached as Exhibit B to the Complaint.

7. IEH is the owner by assignment of all right, title, and interest in U.S. Patent No. 8,822,143 (the “’143 patent”) entitled “Modular Compositing—Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents.” The U.S. Patent and Trademark Office (“USPTO”) duly and legally issued the ’143 patent on September 2, 2014. A copy of the ’143 patent is attached as Exhibit C to the Complaint. A copy of a certificate of correction for the ’143 patent, dated September 2, 2014, is attached as Exhibit D to the Complaint.

8. IEH is the owner by assignment of all right, title, and interest in U.S. Patent No. 9,637,771 (the “’771 patent”) entitled “Modular Compositing—Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents.” The USPTO duly and legally issued the ’771 patent on May 2, 2017. A copy of the ’771 patent is attached as Exhibit E to the Complaint.

THE INVENTIONS OF THE PATENTS-IN-SUIT

9. IEH provides the food industry with testing for microbiological contamination before releasing food into commerce. Producers, manufacturers, and regulators strive to improve the safety and quality of the food, ensuring that it is free of harmful microbiological

contamination, such as E. coli, Listeria, and Salmonella. See '143 Patent Col. 1:49-50; '771 Patent Col. 1:56-57; '584 Patent Col. 1:37-38.

10. In or around 2002, an IEH scientist invented a new method of testing for contamination that has since revolutionized the food industry, and subsequently patented that method in the '584 Patent, the '143 Patent and '771 Patent, and assigned each of them to IEH.

11. The patented method may be used to simultaneously test multiple lots of food for contamination. For example, in the context of meat products, a "lot" of harvested beef trim may consist of a combo-bin containing e.g., 2,000 lbs. of beef trim. For example, the patented method can be used to test five such lots simultaneously.

12. The patented method begins by "separately collecting multiple independent samples" from each lot. '584 Patent Claim 1(a); '143 Patent Claim 1(a); '771 Patent Claim 1(a). In the beef example, this collections step may involve gathering e.g., sixty (60) independent samples (portions/pieces) of beef trim.

13. Those samples are combined together to form a composite sample representative of the first lot. '584 Patent Claim 1(b); '143 Patent Claim 1(b); '771 Patent Claim 1(b). That composited sample is then added to an enrichment medium, often a liquid broth containing nutrients allowing the target microbe (e.g., E. coli) to grow. '584 Patent Claim 1(c); '143 Patent Claim 1(c); '771 Patent Claim 1(c). This enriched composite may be more easily tested for contamination.

14. This process is performed for each of the lots to create multiple enriched composites, one for each lot.

15. Next, the patented method combines a portion from each enriched composite to create a single pooled sample representing all five lots. '584 Patent Claim 1(d); '143 Patent Claim 1(d); '771 Patent Claim 1(d).

16. Finally, the pooled sample is tested to determine whether it contains the target microbe, such as *E. coli* in the beef example. '584 Patent Claim 1(e); '143 Patent Claim 1(e); '771 Patent Claim 1(e).

17. The Asserted Patents teach that, if just one of the lots is contaminated, testing the pooled sample would detect that contamination. *Id.* Thus, if the testing assay does not detect the microbe, ***all five lots*** are considered free of *E. coli*. *Id.* The Asserted Patents refer to this step as “validating” the test lots. *Id.* This allows five lots to be analyzed and validated using a single test.

18. But if the test detects contamination in the pooled sample, not all five lots of beef necessarily have the microbe and need to be destroyed. *Id.* Instead, the remaining portions of the five enriched composites are separately tested to pinpoint the contamination. *Id.*

19. The inventor of the subject patents discovered that, in most instances, the contamination is restricted to only one or two of the five lots. Thus, the invention results in substantial net savings for food producers because less product is destroyed (or otherwise diverted), while simultaneously maintaining the safety of the food chain.

20. The '584, '143 and '771 patents cover this form of testing.

21. Claim 1 of the '143 patent provides a representative example of how those patents describe the inventive method:

1. A method of sampling and testing products for microbes in multiple separate lots, comprising:

a) separately collecting multiple independent samples from each of multiple separate lots, wherein each separate lot is separately sampled by taking said multiple independent samples thereof;

b) separately compositing the collected multiple independent samples from each of the separate lots to provide a corresponding set of separate composited lot samples, wherein each of the separate composited lot samples is attributed to a particular corresponding separate lot;

- c) enriching each of the separate composited test lot samples to provide a set of separate composited test lot samples enriched for the target microbe(s);
- d) removing portions of each separate enriched composited lot sample, and combining the removed portions to provide a pooled modular composite sample; and
- e) testing of the pooled modular composite sample, using a suitable detection assay, for the target microbe(s), wherein when such testing is negative all of said samples that were composited to form the separate composited lot samples are deemed negative for the target microbe(s) and each of the multiple separate lots is validated, and wherein when such testing is positive, each of the individual separate composited lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited lot samples is positive for the target microbe(s), wherein the lots corresponding to any negatively testing composited lot samples are validated.

IEH'S ATTEMPTS TO LICENSE ITS PATENTS TO FSNS

22. IEH has made repeated efforts to license the subject patents to FSNS. As early as 2017, IEH notified FSNS of its infringement of the subject patents. In November 2017, IEH provided John Bellinger of FSNS with licensing rates for testing performed with the inventions of the subject patents. FSNS did not agree to a license.

23. In November 2020, IEH again contacted John Bellinger of FSNS, and asked if FSNS was “interested in resuming our discussions regarding a potential license agreement.” IEH again sent Mr. Bellinger licensing rates for testing performed with the inventions of the subject patents. FSNS never responded to IEH’s licensing inquiries.

FSNS’ INFRINGEMENT

24. FSNS is in the business of, among other things, conducting laboratory testing of agricultural products, crops, equipment, and environmental samples for the presence of microorganisms.

25. On information and belief, among other things, FSNS performs microbiological testing using methods of sampling and testing for microbes in separate lots, including the use of selectively enriched sample “pooling” for microbes (the “FSNS Pooling Methods”).

26. On information and belief, the FSNS Pooling Methods begin by collecting samples from separate lots, such as lots of meat (e.g., beef). FSNS takes multiple independent samples from each of the separate lots. For example, when testing five lots of beef, FSNS takes multiple independent samples (portions/pieces) of beef trim from each of the five lots. On information and belief, FSNS either conducts this step itself or conditions the benefit of pooled testing on its customer(s) performing this sampling step. In the latter scenario, FSNS establishes the manner and timing of the sampling.

27. On information and belief, FSNS separately composites each of the samples from each of the separate lots. For example, again with respect to testing beef, FSNS takes e.g., 60 independent samples (pieces/portions) of beef trim from each of the five lots and separately adds them into five bags. Each bag contains samples drawn from a particular lot beef. On information and belief, FSNS either conducts this step itself or conditions the benefit of pooled testing on its customer(s) performing this compositing step. In the latter scenario, FSNS establishes the manner and timing of the compositing.

28. On information and belief, FSNS separately enriches each of the composite samples. For example, FSNS uses a wet enrichment and separately incubates each of the composite samples for 12 to 24 hours at a temperature between 40 and 45 degrees Celsius.

29. On information and belief, FSNS then removes a portion from each enriched sample and combines those portions together into a pooled composite sample. For example, after incubation, FSNS takes 1 to 2 mL from the five enriched composite samples and combines them into a single pooled sample that is homogenized.

30. On information and belief, FSNS tests the pooled sample using various detection assays. For example, FSNS may use the Atlas STEC EG2 Combo and Salmonella SG2 detection

assays for the analysis and detection of *E. coli* and *Salmonella enterica*. When the tests of the pooled sample return a negative result, FSNS deems all of the sampled lots negative. But when the test of the pooled sample returns a positive result, FSNS uses a detection assay to test each of the separately enriched composite samples. FSNS then separately validates those samples. When any of the individual tests returns a negative result, FSNS deems negative the sampled lots corresponding to those individually enriched samples with a negative result. Conversely, when any of the individual tests returns a positive result, FSNS deems positive the sampled lots corresponding to those individual enriched samples with a positive result.

31. On information and belief, FSNS has and continues to infringe, literally or under the doctrine of equivalents, at least one claim of the '584, '143 and '771 patents, including claim 1 of each patent, by using the FSNS Pooling Methods.

32. On information and belief, FSNS is, and has been, on notice of the '584, '143 and '771 patents since at least as early as October 18, 2017, when IEH sent a letter to FSNS, alerting FSNS to the existence and its infringement of subject patents. This letter was a follow-up to an in-person meeting between IEH and FSNS principals discussing FSNS's infringement of the subject patents.

33. On information and belief, FSNS has continued to infringe the '584, '143 and '771 patents despite an objectively high likelihood that its actions constitute infringement of these valid patents. FSNS's infringement of the '584, '143 and '771 patents has therefore been willful.

34. On information and belief, FSNS's infringing conduct was and is without authority, consent, or license.

35. IEH has suffered irreparable harm and will continue to suffer irreparable harm unless FSNS is enjoined from infringing the '584, '143 and '771 patents. IEH has no adequate remedy at law.

36. IEH is entitled to recover from FSNS the damages sustained by IEH as a result of FSNS's wrongful acts in an amount IEH will prove at trial, including, but not limited to, lost profits and/or a reasonable royalty, together with interest and costs, as well as attorneys' fees, should the Court deem the case to be exceptional.

COUNT I: INFRINGEMENT OF THE '143 PATENT

37. IEH repeats and re-alleges the allegations contained in the preceding paragraphs as if fully set forth herein.

38. Defendant has and continues to infringe, literally and/or under the doctrine of equivalents, at least one claim of the '143 patent, including claim 1, by using the FSNS Pooling Methods.

39. FSNS's use of the FSNS Pooling Methods includes separately collecting multiple independent samples from each of multiple separate test lots, wherein each separate test lot is separately sampled by taking said multiple independent samples thereof. FSNS either conducts this sampling step itself or conditions the benefit of pooled testing on its customer(s) performing this sampling step. In the latter scenario, FSNS establishes the manner and timing of the sampling.

40. FSNS's use of the FSNS Pooling Methods also includes separately compositing the collected multiple independent samples from each of the separate test lots to provide a corresponding set of separate composited test lot samples, wherein each of the separate composited test lot samples is attributed to a particular corresponding separate test lot. FSNS either conducts this compositing step itself or conditions the benefit of pooled testing on its customer(s) performing this compositing step. In the latter scenario, FSNS establishes the manner and timing of the compositing.

41. FSNS's use of the FSNS Pooling Methods further includes enriching each of the separate composited test lot samples enriched for the target microbe.

42. FSNS's use of the FSNS Pooling Methods includes removing portions of each separate enriched composited test lot sample, and combining the removed portions to provide a pooled modular composite sample.

43. FSNS's use of the FSNS Pooling Methods still further includes testing of the pooled modular composite sample, using a suitable detection assay, for the target microbe, wherein when such testing is negative all of said samples that were composited to form the separate composited test lot samples are deemed negative for the target microbe and each of the multiple separate test lots is validated, and wherein when such testing is positive, each of the individual separate composited test lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited test lot samples is positive for the target microbe, wherein the test lots corresponding to any negatively testing composited test lot samples are validated.

44. FSNS's infringing conduct was and is without authority, consent, or license.

45. FSNS is, and has been, on notice of the '143 patent since at least as early as October 18, 2017.

46. Upon information and belief, FSNS's infringement of the '143 patent has been willful.

47. IEH has suffered irreparable harm and will continue to suffer irreparable harm unless FSNS is enjoined from infringing the '143 patent.

48. IEH has been damaged and continues to be damaged by FSNS's infringement of the '143 patent.

COUNT II: INFRINGEMENT OF THE '771 PATENT

49. IEH repeats and re-alleges the allegations contained in the preceding paragraphs as if fully set forth herein.

50. FSNS has and continues to infringe, literally or under the doctrine of equivalents, at least one claim of the '771 patent, including claim 1, by using the FSNS Pooling Methods.

51. FSNS's use of the FSNS Pooling Methods includes separately collecting multiple independent samples from each of multiple separate lots, wherein each separate lot is separately sampled by taking said multiple independent samples thereof. FSNS either conducts this sampling step itself or conditions the benefit of pooled testing on its customer(s) performing this sampling step. In the latter scenario, FSNS establishes the manner and timing of the sampling.

52. FSNS's use of the FSNS Pooling Methods also includes separately compositing the collected multiple independent samples from each of the separate lots to provide a corresponding set of separate composited lot samples, wherein each of the separate composited lot samples is attributed to a particular corresponding separate lot. FSNS either conducts this compositing step itself or conditions the benefit of pooled testing on its customer(s) performing this compositing step. In the latter scenario, FSNS establishes the manner and timing of the compositing.

53. FSNS's use of the FSNS Pooling Methods further includes enriching each of the separate composited lot samples to provide a set of separate composited lot samples enriched for the target microbe.

54. FSNS's use of the FSNS Pooling Methods includes moving portions of each separate enriched composited lot sample, and combining the removed portions to provide a pooled modular composite sample.

55. FSNS's use of the FSNS Pooling Methods still further includes testing of the pooled modular composite sample, using a suitable detection assay, for the target microbe, wherein when such testing is negative all of said samples that were composited to form the separate composited lot samples are deemed negative for the target microbe and each of the multiple separate lots is validated, and wherein when such testing is positive, each of the individual separate composited lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited lot samples is

positive for the target microbe, wherein the lots corresponding to any negatively testing composited lot samples are validated.

56. FSNS's infringing conduct was and is without authority, consent, or license.

57. FSNS is, and has been, on notice of the '771 patent since at least as early as October 18, 2017.

58. Upon information and belief, FSNS's infringement of the '771 patent has been willful.

59. IEH has suffered irreparable harm and will continue to suffer irreparable harm unless FSNS is enjoined from infringement of the '771 patent.

60. IEH has been damaged and continues to be damaged by FSNS's infringement of the '771 patent.

COUNT III: INFRINGEMENT OF THE '584 PATENT

61. IEH repeats and re-alleges the allegations contained in the preceding paragraphs as if fully set forth herein.

62. Defendants has and continues to infringe, literally and/or under the doctrine of equivalents, at least one claim of the '584 patent, including claim 1, by using the FSNS Pooling Methods.

63. FSNS's use of the FSNS Pooling Methods includes collecting a plurality of portions from each of a plurality of separate operationally-linked test lots of beef, each to be validated for release into commerce, the test lots each comprising an assemblage of one or more specimens from which the portions are collected, wherein each test lot is separately sampled to conform to a statistical-based sampling plan specifying, for a particular microbial agent or organism, a number of portions to be taken sufficient to provide for validation and release of the test lot into commerce. FSNS either conducts this collecting step itself or conditions the benefit of pooled testing on its customer(s) performing this collecting step. In the latter scenario, FSNS establishes the manner and timing of the collecting.

64. FSNS's use of the FSNS Pooling Methods also includes combining the collected conforming plurality of portions corresponding to each of the separate test lots to provide a corresponding set of separate test lot samples, wherein each separate test lot sample is attributed to a particular corresponding separate test lot. FSNS either conducts this combining step itself or conditions the benefit of pooled testing on its customer(s) performing this combining step. In the latter scenario, FSNS establishes the manner and timing of the combining.

65. FSNS's use of the FSNS Pooling Methods further includes incubating the set of separate test lot samples under conditions suitable to allow levels of a target microbial agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples, to provide a set of separate test lot samples enriched for the target microbial agent or organism.

66. FSNS's use of the FSNS Pooling Methods further includes removing portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample.

67. FSNS's use of the FSNS Pooling Methods still further includes testing of the modular composite sample, using a suitable detection assay, for the target microbial agent or organism, wherein when such testing is negative all of said separate test lots are validated for release into commerce, and wherein when such testing is positive, each of the individual separate test lots are validated for release into commerce, according to the statistical-based sampling plan, by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining a negative test result for each test lot, wherein the enrichment described above, prior to removing portions as described above, is sufficient to enable said validation of individual separate test lots with no requirement for further enrichment thereof, and with no requirement for further sampling, as described above.

68. FSNS's infringing conduct was and is without authority, consent, or license.

69. FSNS is, and has been, on notice of the '584 patent since at least as early as October 18, 2017.

70. Upon information and belief, FSNS's infringement of the '584 patent has been willful.

71. IEH has suffered irreparable harm and will continue to suffer irreparable harm unless FSNS is enjoined from infringing the '584 patent.

72. IEH has been damaged and continues to be damaged by FSNS's infringement of the '584 patent.

REQUEST FOR RELIEF

A. IEH respectfully requests that the Court enter judgment:

B. Declaring that FSNS has infringed U.S. Patent Nos. 7,534,584, 8,822,143, and 9,637,771;

C. Declaring that FSNS's infringement has been willful;

D. Awarding IEH damages adequate to compensate for FSNS's infringing activities, including supplemental damages for any post-verdict infringement up until entry of the final judgment with an accounting as needed, together with prejudgment and post-judgment interest on the damages awarded; all of these damages to be enhanced in an amount up to treble the amount of compensatory damages under 35 U.S.C. § 284;

E. Declaring that this case is exceptional under 35 U.S.C. § 285 and awarding IEH its reasonable costs and expenses of litigation, including attorneys' and experts' fees; and

F. Granting a permanent injunction pursuant to 35 U.S.C. § 283 enjoining FSNS, its agents, employees, officers, attorneys, successors, assigns, and all persons in active concert or participation with them, from further acts of infringement of United States Patent Nos. 7,534,584, 8,822,143, and 9,637,771 and from using methods or making, offering for sale, or selling products that infringe one or more of the independent claims of either patent either literally or under the doctrine of equivalents; and

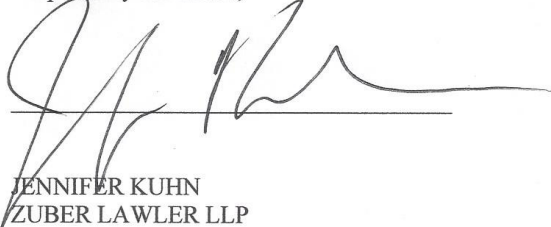
G. Awarding IEH such other and further relief as the Court may deem just and proper.

JURY DEMAND

IEH demands a trial by jury on all issues so triable.

Dated: February 25, 2021.

Respectfully submitted,



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